

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### The Effect of transcranial direct stimulation of different brain cortex areas plus the traditional physical therapy on pain intensity and clinical functional ability of subjects with knee osteoarthritis: “A randomised controlled trial”

#### Protocol summary

##### Study aim

the effect of transcranial direct current stimulation of different regions of the cerebral cortex with the traditional physiotherapy treatment on pain intensity and clinical functional ability of people with knee osteoarthritis

##### Design

A: PT with M1 a-tDCS B: PT with S1 a-tDCS C: PT with DLPFC1 a-tDCS D: PT with Sham tDCS Randomization: simple sample size: cochrane formula

##### Settings and conduct

This study is a double-blind, randomized controlled trial, that will be carried out at the Musculoskeletal Rehabilitation Center of Ahvaz Rehabilitation school. The assessor physiotherapist and participants will be blind. After initial evaluation, they will be treated ten sessions for two weeks

##### Participants/Inclusion and exclusion criteria

1- Individuals aged 50-70 years 2- Individuals with grades 2 and 3 of OA to the diagnosis of orthopedics by Kellgren and Lawrence system 3. Have at least 3 signs of the 6 clinical symptoms of American College of Rheumatology 4- People with dominant right leg involvement (in the case of bilateral, the right lesion is also dominant) 5- Minimal pain 4 according to the visual scale of pain 6. People with limited knee range

##### Intervention groups

A: PT with M1 a-tDCS B: PT with S1 a-tDCS C: PT with DLPFC a-tDCS D: PT with Sham tDCS

##### Main outcome variables

Pain; function; range of motion; strength

#### General information

##### Reason for update

##### Acronym

tDCS

##### IRCT registration information

IRCT registration number: **IRCT20181216042010N1**

Registration date: **2018-12-25, 1397/10/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-12-25, 1397/10/04**

Update count: **0**

##### Registration date

2018-12-25, 1397/10/04

##### Registrant information

###### Name

Fatemeh Rahimi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 4331 4954

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rahimi.f@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of transcranial direct stimulation of different brain cortex areas plus the traditional physical therapy on pain intensity and clinical functional ability of subjects with knee osteoarthritis: "A randomised controlled trial"

**Public title**

The Effect of transcranial direct stimulation of different brain cortex areas plus the traditional physical therapy on pain and function of subjects with knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Individuals aged 50-70 years Individuals with grades 2 and 3 of OA to the diagnosis of orthopedics by System Kellgren and Lawrence Having at least 3 signs of the 6 clinical symptoms of the American College of Rheumatology People with dominant right leg involvement (in the case of bilateral, the right lesion is also dominant) Minimal pain 4 according to the visual scale of pain

**Exclusion criteria:**

Having knee surgery for the last six months Replacing the knee joint or tibia osteotomy on the affected side Neurological conditions affecting organ function (Parkinson's disease, stroke and multiple sclerosis) Inability to walk without help History of another rheumatic disease that causes secondary osteoarthritis People with lack of sensation and epilepsy whom pain modification techniques are prohibited

**Age**

From **50 years** old to **70 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is a simple randomization method that is performed using 4 sealed envelopes containing group names based on the type of intervention.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The assessor physiotherapist and participants are blind

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

NO

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Ahvaz Jundishapour University of Medical Sciences

**Street address**

Golestan high way

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61357- 15794

**Approval date**

2018-10-20, 1397/07/28

**Ethics committee reference number**

IR.AJUMS.REC.1397.519

**Health conditions studied****1****Description of health condition studied**

knee osteoarthritis

**ICD-10 code**

M17.1

**ICD-10 code description**

Unilateral primary osteoarthritis of knee

**Primary outcomes****1****Description**

pain

**Timepoint**

before initiation of treatment, 10 session, 1 month ago

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

function

**Timepoint**

before initiation of treatment, 10 session, 1 month ago

**Method of measurement**

questionnaire and tests

**2****Description**

strength of muscle

**Timepoint**

before initiation of treatment, 10 session, 1 month ago

**Method of measurement**

dynamometer

### 3

#### **Description**

range of motion

#### **Timepoint**

before initiation of treatment, 10 session, 1 month ago

#### **Method of measurement**

goniameter

## **Intervention groups**

### 1

#### **Description**

Intervention group: traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with trans-cranial direct current stimulation of primary motor cortex for ten sessions

#### **Category**

Rehabilitation

### 2

#### **Description**

Intervention group: traditional Physiotherapy traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with transcranial direct current stimulation of primary sensory cortex for ten sessions

#### **Category**

Rehabilitation

### 3

#### **Description**

Intervention group: traditional Physiotherapy traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with transcranial direct current stimulation of dorsolateral perfrontal cortex for ten sessions

#### **Category**

Rehabilitation

### 4

#### **Description**

Control group: traditional Physiotherapy traditional Physiotherapy(Ultrasound, Infra-Red, Trans- cutaneous Electrical Nerve Stimulation, Exercise therapy) with sham transcranial direct current stimulation for ten sessions

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Clinic of rehabilitation school,Jundishapour university,

Golestan Highway, Ahvaz

#### **Full name of responsible person**

Gholamhosein Nassaj

#### **Street address**

Clinic of rehabilitation school,Jundishapour university, Golestan Highway, Ahvaz

#### **City**

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#### **Province**

Khouzestan

#### **Postal code**

33133- 611357

#### **Phone**

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#### **Email**

nassadj@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Ahvaz University of Medical Sciences

##### **Full name of responsible person**

Mohammad Badavi

##### **Street address**

Golestan highway, Ahvaz,Iran

##### **City**

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+98 61 3336 2414

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##### **Email**

itc@ajums.ac.ir

##### **Web page address**

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Ahvaz University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

empty

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Gholmhosein Nassaj

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

### Contact

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**Position**

Assistant Professor

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Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Rahimi

**Position**

Ph.D candidate

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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Rahimi.f@ajums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The total potential data can be shared after unidentified individuals

**When the data will become available and for how long**

6 months after publishing

**To whom data/document is available**

Data will only be available to researchers in academic and scientific institutes

**Under which criteria data/document could be used**

If someone want to do a similar research project

**From where data/document is obtainable**

Gholamhosein Nassaj

**What processes are involved for a request to access data/document**

through E-mail and note the cause and purpose

**Comments**